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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

SALLBERG et al.

Serial No.: 09/466,035

Group Art Unit: 1635

Filing Date: RCE filed herewith

Examiner: P. Paras, Jr.

Title: COMPOSITIONS AND METHODS FOR TREATING  
INTRACELLULAR DISEASES

INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. § 1.97

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

The information listed below may be material to the examination of the above-identified application. Copies of the information and completed PTO-1449 forms are submitted herewith. The Examiner is respectfully requested to make this information of official record in the application. The information includes:

United States Patent No. 5,589,466 issued December 31, 1996 to Felgner *et al.*;

United States Patent No. 5,766,602 issued June 16, 1998 to Xiong *et al.*;

Barnett, *et al.*, "Vaccination With HIV-1 gp120 DNA Induces Immune Responses That Are Boosted by a Recombinant gp120 Protein Subunit," *Vaccine* 15(8):869-873 (1997);

Butini, *et al.*, "Comparative analysis of HIV-specific CTL activity in lymphoid tissue and peripheral blood," Abstract J 306, *J. Cell. Biochem.*, Suppl. 18B:147 (1994);

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- Cohen, "Jitters Jeopardize AIDS Vaccine Trials," *Science* 262:980-981 (1993);
- Cooney, *et al.*, "Enhanced immunity to human immunodeficiency virus (HIV) envelope elicited by a combined vaccine regimen consisting of priming with a vaccinia recombinant expressing HIV envelope and boosting with gp160 protein," *Proc. Natl. Acad. Sci. USA* 90:1882-1886 (1993);
- Cranage, *et al.*, "Parameters of Protection with Live Attenuated Simian Immunodeficiency Virus," *Journal of Medical Primatology* 24:182-183 abstract 23 (1995);
- Daniel, *et al.*, "High-Titer Immune Responses Elicited by Recombinant Vaccinia Virus Priming and Particle Boosting Are Ineffective in Preventing Virulent SIV Infection," *AIDS Research and Human Retroviruses* 10(7):839-851 (1994);
- Doe, *et al.*, "Induction of Cytotoxic T Lymphocytes by Intramuscular Immunization with Plasmid DNA is Facilitated by Bone Marrow-Derived Cells," *Proc. Natl. Acad. Sci. USA* 93:8578-8583 (1996);
- Fleury, *et al.*, "Memory Cytotoxic T Lymphocyte Responses in Human Immunodeficiency Virus Type 1 (HIV-1)-Negative Volunteers Immunized with a Recombinant Canarypox Expressing gp160 of HIV-1 and Boosted with a Recombinant gp 160," *The Journal of Infectious Diseases* 174:734-738 (1996);
- Fuller, *et al.*, "A Qualitative Progression in HIV Type 1 Glycoprotein 120-Specific Cytotoxic Cellular and Humoral Immune Responses in Mice Receiving a DNA-Based Glycoprotein 120 Vaccine," *AIDS Research and Human Retroviruses* 10(11):1433-1441 (1994);
- Fuller, *et al.*, "DNA Vaccines," *Journal of Medical Primatology* 24(4):182-183 abstract 26 (1995);
- Fuller, *et al.*, "Induction of Immunodeficiency Virus-Specific Immune Responses in Rhesus Monkeys Following Gene Gun-Mediated DNA Vaccination," *J. Med. Primatol.* 25:236-241 (1996);
- Fuller, *et al.*, "Enhancement of Immunodeficiency Virus-Specific Immune Responses in DNA-Immunized Rhesus Macaques," *Vaccine* 15(8):924-926 (1997);

Gorse, *et al.*, "Vaccine-Induced Antibodies to Native and Recombinant Human Immunodeficiency Virus Type 1 Envelope Glycoproteins," *Vaccine* 12(10):912-918 (1994);

Graham, *et al.*, "Augmentation of Human Immunodeficiency Virus Type 1 Neutralizing Antibody by Priming with gp 160 Recombinant Vaccinia and Boosting with rgp 160 in Vaccinia-Naive Adults," *The Journal of Infectious Diseases* 167:533-537 (1993);

Haynes, "Scientific and Social Issues of Human Immunodeficiency Virus Vaccine Development," *Science* 260:1279-1286 (1993);

Haynes, *et al.*, "In Vivo Delivery of HIV and SIV Antigen-Encoding Vectors by Particle Bombardment as an Alternative to Live Recombinant Viruses for the Induction of Humoral and Cellular Immunity," *AIDS Research and Human Retroviruses* 9(1):S75 (1993);

Hu, *et al.*, "Neutralizing Antibodies Against HIV-1 BRU and SF2 Isolates Generated in Mice Immunized with Recombinant Vaccinia Virus Expressing HIV-1 (BRU) Envelope Glycoproteins and Boosted with Homologous gp160," *AIDS Res. Hum. Retro.* 7(7):615-620 (1991);

Hu, *et al.*, "Protection of Macaques Against SIV Infection by Subunit Vaccines of SIV Envelope Glycoprotein gp 160," *Science* 255:456-459 (1992);

Jolly, "Viral Vector systems for gene therapy," *Can. Gene. Ther.* 1:51-64 (1994);

Klaniecki, *et al.*, "Immune response to HIV-1 envelope and core antigens in protection of macaques against chimeric SHIV challenge," *J. Med. Primatol.* 24:182-183 abstract 25 (1995);

McElrath, *et al.*, "Immune Responses Elicited by Recombinant Vaccinia-Human Immunodeficiency Virus (HIV) Envelope and HIV Envelope Protein: Analysis of the Durability of Responses and Effect of Repeated Boosting," *The Journal of Infectious Diseases* 169:41-47 (1994);

Miller, *et al.*, "Targeted vectors for gene therapy," *The FASEB J.* 9:190-199 (1995);

Pialoux, *et al.*, "A Prime-Boost Approach to HIV Preventive Vaccine using a Recombinant Canarypox Virus Expressing Glycoprotein 16 (MN) Followed by a Recombinant Glycoprotein," *AIDS Research and Human Retroviruses* 11(3):373-381 (1995);

Salmon-Céron, *et al.*, "Safety and Immunogenicity of a Recombinant HIV Type 1 Glycoprotein 160 Boosted by a V3 Synthetic Peptide in HIV-Negative Volunteers," *AIDS Research and Human Retroviruses* 11(12):1479-1486 (1995);

Tang, *et al.*, "Genetic Immunization is a simple method for eliciting an immune response," *Nature* 356:152-154 (1992);

Ulmer, *et al.*, "Heterologous Protection Against Influenza by Injection of DNA Encoding a Viral Protein," *Science* 259:1745-1749 (1993); and

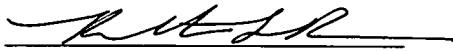
Wang, *et al.*, "Gene Inoculation Generated Immune Responses Against Human Immunodeficiency Virus Type 1," *Proc. Natl. Acad. Sci. USA* 90:4156-4160 (1993).

This Information Disclosure Statement under 37 CFR § 1.97 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

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PATENT

Respectfully submitted,

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